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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/674,597	04/09/2001	Zheng Xin Dong	00537-169002	1308
37903	7590	09/19/2007	EXAMINER	
DAWN JANELLE AT BIOMEASURE INC. 27 MAPLE STREET MILFORD, MA 01757			WEGERT, SANDRA L	
			ART UNIT	PAPER NUMBER
			1647	
			MAIL DATE	DELIVERY MODE
			09/19/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/674,597

Applicant(s)

DONG ET AL.

Examiner

Sandra Wegert

Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 6/25/07.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11 and 52-55 is/are pending in the application.
- 4a) Of the above claim(s) 54 and 55 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11, 52, 53 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Art Unit: 1647

Detailed Action

Status of Application, Amendments, and/or Claims.

A request for continued examination (RCE) under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. This application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid.

The Amendments and Response, submitted 25 June 2007, have been entered. Claims 1-10 and 12-51 have been canceled. Claim 11 has been amended. Claims 52-55 are new. New Claims 54 and 55 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected Inventions, there being no allowable generic or linking claim. The restriction requirement was made final in the Office Action of 25 January 2007.

Claims 11, 52 and 53 are under examination in the Instant Application.

Withdrawn Objections And/or Rejections

-Duplicate claims

The objection to claim 12 for being a substantial duplicate of claim 11 is withdrawn. Applicants cancelled claim 12 (25 June 2007).

Claim Rejections - 35 USC § 112, first paragraph-Written Description

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process

Art Unit: 1647

of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of Claims 9, 10, 13-15 and 23-29 under 35 U.S.C. 112, first paragraph, written-description is *withdrawn*. Applicants cancelled Claims 9, 10, 13-15 and 23-29. The reasons for this rejection under 35 U.S.C. § 112 are set forth at pp. 4-7 of the previous Office Action (25 June 2007). This rejection does not apply to newly-submitted claims 52 and 53, since those claims explicitly set out the peptides of the claimed genus. In addition, applicants made and tested the claimed peptides (see Declaration filed under 37 CFR § 1.132, filed 25 June 2007).

Claim Rejections- Double-Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The rejection of Claims 9-15 and 23-29 under the judicially created doctrine of double patenting is *withdrawn* for Patent 5,717,062, based on applicants' arguments. Applicants cancelled claims 9, 10, 12-15 and 23-29 and pointed out that Claims 11, 52 and 53 do not

Art Unit: 1647

encompass compounds that will form cyclic compounds, as embraced by the '062 Patent (25 June 2007).

35 U.S.C. § 102

The following are quotations of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The rejection of Claims 9-15 and 23-29 under 35 U.S.C. 102(b) as being unpatentable over Gardella, et al, (1996, J. Biol. Chem., 271(33): 19888-19893) is *withdrawn*. Applicants cancelled claims 9, 10, 12-15 and 23-29. Amended claim 11, and new claims 52 and 53 do not read on the compounds disclosed in Gardella, et al.

The rejection of Claim 9 under 35 U.S.C. 102(b) as being unpatentable over Neugebauer and Willick, (1993, Peptides 1992, C.H. Schneider and A.N. Eberle (eds), ESCOM Science Publishers) is *withdrawn*. Applicants cancelled claim 9 (25 June 2007).

Likewise, the rejection of claim 9 under 35 U.S.C. 102(b) for being unpatentable over Willick, et al, 1996 (U.S. Patent 5,556,940) is *withdrawn*. Applicants cancelled claim 9 (25 June 2007).

Art Unit: 1647

The rejection of Claims 9, 10, 12-15 and 23-29 under 35 U.S.C. 102(e) as being anticipated by US Patent 5,717,062 (Chorev) is *withdrawn*. The rejection was made over claims 1-16 of U. S. Patent No. 5,717,062. Applicants cancelled claims 9, 10, 12-15 and 23-29. Amended claim 11, and new claims 52 and 53 do not read on the compounds disclosed in the '062 Patent.

Maintained/New Objections and/or Rejections

Claim Rejections- Double-Patenting

The rejection of Claims 11, and new claims 52 and 53 under the judicially created doctrine of double patenting, is *maintained*. The rejection was made over claims 1-23 of U. S. Patent No. 5,723,577 (25 January 2007). The rejection is now made over claims 1, 2, 3, 4, 9, 13, 18 and 19 of the '577 patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: The claimed analogues of the instant Application are the same structures encompassed by claims 1, 2, 3, 4, 9, 13, 18 and 19 of Patent 5,723,577. The claimed analogues of Patent 5,723,577 are the same as the PTH analogues of the instant Application and would therefore possess the same *inherent* characteristics concerning PTH2 binding affinity and

Art Unit: 1647

efficacy (Kd and EC50, respectively; see Table I of Patent 5,723,577 for PTH-R binding affinities).

Applicants argue essentially (Remarks, p. 8, 25 June 2007) that the claims of the instant Application recite the functional limitation of selectively binding to the PTH2 receptor, a teaching that was "unappreciated" in the '577 Patent.

Applicants arguments (p. 7) are essentially correct in that the PTH2 receptor was not known at the time of filing of the '577 patent. Thus the newly-discovered property of binding the PTH2 receptor could not have been included in the patent. However, this does not change the essential point of the rejection that "the discovery of a previously unappreciated property of a prior art composition [] does not render the old composition patentably new to the discoverer" (MPEP § 2112-I).

As argued previously (25 January 2007) Applicants are claiming chemical compounds, not methods that make use of the "unappreciated" functional limitation. All of the peptides claimed are encompassed by claims 1, 2, 3, 4, 9, 13, 18 and 19 in the '577 patent. Applicants cannot negate the obviousness of the present invention by inserting additional language not found in the '577 patent. The compounds of the '577 patent would inherently possess the same properties as those of the present invention, whether that language was used or not (*in re Skoner*, 517 F.2d 947, 950 (C.C.P.A. 1975), 186 U.S.P.Q. 80, 82 (1975)). The burden thus shifts to the Applicants to provide evidence that the peptides of the '577 patent do NOT possess the functional limitations recited in the Applicants claims (see *In re Crish*, 393 F.3d 1253, 1258, 73 USPQ2d 1364, 1368 (Fed. Cir. 2004), and MPEP § 2112.01 and § 2141).

Art Unit: 1647

The rejection of Claims 11 and new claims 52 and 53, under the judicially created doctrine of double patenting, is *maintained* over US Patent No. 5,955,574, for reasons of record. Applicants did not discuss the specifics of the rejection (Remarks, p. 9). The rejection was made over claims 1-14 of U. S. Patent No. 5,955,574 (25 January 2007). The rejection is now made over claims 1-4 of the '574 patent, which claims specifically embrace the compounds listed in instant claims 11, 52 and 53.

35 U.S.C. § 102

The rejection of claims 11, 52 and 53 under 35 U.S.C. 102(e) as being anticipated by US Patent 5,955,574 (Dong, et al) is *maintained*. See the obviousness-type double patenting rejection (above). Applicants do not specifically address this rejection, except to state that Instant claims recite only a single invention (Remarks, p. 11). However, the peptide in claim 11, for example, is embraced by claims 1-4 of the '574 Patent.

Conclusion

No claim is allowed.

Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Wegert whose telephone number is (571) 272-0895. The examiner can normally be reached Monday - Friday from 9:00 AM to 5:00 PM (Eastern Time).

Application/Control Number: 09/674,597

Page 8

Art Unit: 1647


If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Manjunath Rao, can be reached at (571) 272-0939.

The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (in USA or CANADA) or 571-272-1000.

SLW

15 September 2007


EILEEN B. O'HARA
PRIMARY EXAMINER